

EXHIBIT 38

Food and Drug Administration Office of Regulatory Affairs**Collection Report****For Sample Number: 462753**

This is an accurate reproduction of the original electronic record as of: 03/09/2010

Flag	Flag Remarks				
Survey Sample	CDER Survey 2008-800				
Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic	Other-Survl	Official	0887041	Completed
FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
3006697890	03/21/2008	63FCC06	Manufacturer	56008A	3
Compliance Num	Country of Origin				
	United States				
Related Smpl Num	Position Class	Sampling District	NDC Number	Permit Number	Storage Rqrmnt.
462744	DAP	SAN-DO	51079-946-66		Ambient
Dealer is Consumer	Crx/DEA Schedule	Recall Num	Consumer Compl. Num	Brand Name	
No				Digitex	

Product Description

Digoxin Tablets, 250 mcg, RX, single ingredient

Product Label

See continuation.

Reason for Collection

FY 2008 Low Cost Generic Drug Sample Survey 2008-800 (CP 7356.008). Analyze for Uniformity of Dosage Units; Dissolution; Identification

MFG Codes

Printed in ink on side of bottle: "Lot No.: 8A332"

Expiration Date

"Exp. Date: 7/09"

Firm Legal Name

Walmart Stores Inc

Address

13232 11th Avenue Hanford, CA 93230-9591 US

Type of Firm

Dealer

Firm FEI

3005072736

FCE

AMIDE PHARMACEUTICALS INC.

101 E Main St Little Falls, NJ 07424-5608 US

Manufacturer

3006697890

Size of Lot

(b)(4) Tablets(b)(4) bottles

Est. Value**Rept Type**

FDA484

Carrier Name**Date Shipped****Description of Sample**

Sample consists of two boxes of Digoxin Tablets, USP, 250 mcg

Method of Collection

Collected at random from lot on shelves at dealer.

How Prepared

Sample id'd as below and placed into brown paper bag. Brown paper bag id'd as below and sealed as below. Packed to ship.

Collector's Identification on Package and/or Label

"462753 03/21/08 LCL"

Collector's Identification on Seal

"462753 03/25/08 Lillian C. Lopez"

Sample Delivered To

Fed-Ex

Date Delivered

03/25/2008

Orig C/R & Records To

SAN-DO

Lab w/Split Sample

0

Lab

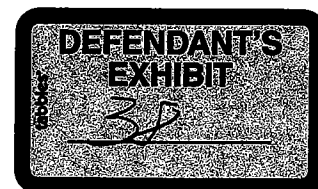
NRL

Document Number**Document Date****Document Type****Document Remarks****Remarks**

Sample collected on 3-21-08, held under lock and key, and sealed and shipped on 3-25-08.

Date: 03/09/2010

Page: 1 of 3



**Food and Drug Administration Office of Regulatory Affairs
Collection Report**

For Sample Number: 462753

This is an accurate reproduction of the original electronic record as of 03/09/2010

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
\$0.00	No Charge	No	No	Lillian C Lopez
Name of Signer	Date & Time of Signature			Meaning
Lillian C Lopez	03/25/2008 01:22 PM ET			Collector

ate: 03/09/2010

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 462753

This is an accurate reproduction of the original electronic record as of 03/09/2010

Continuation:

Product Label

Product in white box labeled in part: "**** NDC 51079-946 -66 ***DIGITEK*** (DIGOXIN TABLETS, USP) *** 250 mcg (0.25 mg)*** 180 Tablets *** Lot No.: 8A332 Exp. Date: 7/09***".

Food and Drug Administration Office of Regulatory Affairs**Summary Report****For Sample Number:** 462753**TD Sample Number:****Import Sample Number:**

This is an accurate reproduction of the original electronic record as of 09/23/2008

Sample Class: Normal Everyday Sample
Survey Sample**Sample Origin:** Domestic
Sample Type: Official**Sample Basis:** Surveillance
Collecting District: SAN-DO**Home District:****Orig C/R and Records To:** SAN-DO**Collection PACs:** 56008A**Product Name:** Digoxin (Cardiotonic); Human - Rx/Single Ingredient; Delayed Release Tablets**Product Description:** Digoxin Tablets, 250 mcg, RX, single ingredient**Collection Reason:** FY 2008 Low Cost Generic Drug Sample Survey 2008-800 (CP 7356.008). Analyze for Uniformity of Dosage Units; Dissolution; Identification

Lab: NRL	Split Num 0	Date Received: 03/26/2008	Date Out of Lab: 09/23/2008
District		District Conclusion	District
Conclusion:		Made By:	
Disposition		Disposition	Disposition
Reason:		Authorized By:	Authorized Date

Performing Org	PAC	LID	PAF	Compliance No	Lab Class-Description	Laboratory Status
NRL-DCB-G	56008A		DRT		1 - In Compliance	Completed

Lab Conclusion

product meets specifications for Identification, Dissolution, and Content Uniformity.

Lab Conclusion Date**Lab Conclusion Made By**

09/23/2008

Mathew, Samuel K

RECEIVED

OCT -- 6 2008

FDA -- SJN
COMPLIANCE BRANCH

FLAG Original

ANALYST WORKSHEET		1. PRODUCT DIGITEK (DIGOXIN TABLETS, USP) 250 mcg(0.25 mg)		2. SAMPLE NUMBER 462753	
3. SEAL'S <input type="checkbox"/> NONE <input checked="" type="checkbox"/> INTACT <input type="checkbox"/> BROKEN		4. DATE REC'D 4/3/08		5. RECEIVED FROM Elvis Leslie	
6. DISTRICT OF LABORATORY NRL					
7. DESCRIPTION OF SAMPLE One brown, paper bag officially sealed, "462753 03/25/08 Lillian C. Lopez CST", containing two product cartons identified "462753 03/21/08 LCL Sub 1 of 2" and "462753 03/21/08 LCL Sub 2 of 2", respectively. An FDA 525 is attached to the sample.					
8. NET CON-TENTS <input type="checkbox"/> NOT APPLICABLE <input checked="" type="checkbox"/> NOT DETERMINED UNITS EXAMINED		DECLARE/UNIT 180 tablets AMOUNT FOUND _____ % OF DECLARED _____		9. LABEL-ING 1 ORIGINAL(S) SUBMITTED 1 COPIES SUBMITTED <input type="checkbox"/> NONE	
10. SUMMARY OF ANALYSIS Container: White, rectangular, cardboard carton approximately 14.5 cm x 6.5 cm x 7 cm. Carton contains 6 intact, rectangular, foil, blister packs. Each pack contains 30 tablets. Each individual pack is stored in a separate, white, plastic case. Labeling: Carton has a commercially-printed, rectangular, paper, stick-on label. Commercially-printed product insert is inside carton. Plastic case has a similar commercially-printed label. Code: " Lot No.: 8A332 " and " Exp. Date: 7/09 " printed on the carton label and the back of each blister pack. Product: Round, biconvex, solid, white tablet. Tablet is unmarked and unscored on one side. Opposite side is 1/2-scored with markings "B" and "146". Tablet is approximately 7.5 mm in diameter. Analysis: Identification, Dissolution, and Content Uniformity. Method: USP 30 - NF 25, p. 1943. Results: See general continuation sheet page 2.					
11. RESERVE SAMPLE Original, brown, paper bag officially sealed " 462753 9/22/08 Valentino Fiorella Analyst" containing one open and one intact product carton. Open carton is additionally identified " VF 4/3/08 ". Plastic case with used blister pack containing 11 tablets is identified " #462753 4/3/08 VF Sub 2 of 2". Sample returned to the sample custodian.					
12 a. ANALYST SIGNATURE (Broke Seal <input checked="" type="checkbox"/>) <i>Valentino Fiorella</i>		13. WORK-SHEET CHECK		a. BY <i>J. Mathew</i>	
b.				b. DATE 9/23/08	
c.		14. DATE REPORTED		9/23/08	

Spl. #462753
Back of page 1

VF 9/22/04

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.25 mg)	SAMPLE NO. 462753
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RESULTS:

Identification

The retention time of the major peak in the chromatogram of the sample preparation corresponds to that in the chromatogram of the standard preparation. Complies

Content Uniformity
(See computer printout pages 6 - 7 for complete results)

Range: 93.4 % to 105.7 %; Average (X): 98.7 %;

RSD: 3.5 %; s: 3.47

Acceptance Value (AV) = 8.3 %

(Limit: AV ≤ 15.0 % unless otherwise specified in the individual monograph)

Dissolution
(See least squares line fitting pages 11 - 12 for complete results)

Range: 89.3 % to 105.7 % ; Avg.: 98.2 %

(Limit: Each unit is NLT Q+5% (Q=80%) for 6 units tested (Stage 1))

ANALYST(S) <i>Valentino Fiorelli</i>	ANALYST NO. 113	PAGE 2 OF 62 PAGES
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SPL# 462753
Back of Page 2
5/12/08
VF

DIGOXIN TABLETS

(USP 30-NF 25, p.1943)

Reference Std:

USP Digoxin RS # 1200000-05, Lot 00B096, dried in vacuum at 105°C for 1 hour prior to use. For quantitative applications, use a value of 0.961 mg of digoxin per mg on the dried basis.

Reagents: Fisher Scientific Acetonitrile, Lot 073938 (Rec'd 11/1/07)
Sigma Digoxigenin, Lot No. 016K3777 (Rec'd 2/6/08)

Filter: PALL Life Sciences Acrodisc 25 mm Syringe Filter with 0.45 um Nylon Membrane, Lot A10529577

Identification

The retention time of the major peak in the chromatogram of the sample preparation corresponds to that in the chromatogram of the standard preparation. Complies

Content Uniformity

Mobile Phase: Water/Acetonitrile (74/26)

System Suitability Solution

(Balance: Cahn C-31 Microbalance, FDA No. 5004472 - QA by G.Lehr on 1/14/08)

4.025 mg USP Digoxin RS + 4.122 mg Digoxigenin

----> 100.0 ml Diluted Alcohol

Standard Solution 1 (CCV)

(Balance: Cahn C-31 Microbalance, FDA No. 5004472 - QA by G.Lehr on 1/14/08)

2.522 mg USP Digoxin RS ----> 100.0 ml Diluted Alcohol

Standard Solution 2 (ICV/Check Std.)

(Balance: Cahn C-31 Microbalance, FDA No. 5004472 - QA by G.Lehr on 1/14/08)

2.505 mg USP Digoxin RS ----> 100.0 ml Diluted Alcohol

Sample Solution

For each of 10 tablets tested:

1 tablet(0.25 mg) ----> 10.0 ml Diluted Alcohol ----> Filter

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.25 mg)	SAMPLE NO 462753
ANALYST(S) <i>Valentino Anelli</i>	ANALYST NO. 113	PAGE 3 OF 12 PAGES

SPL# 462753
 Back of Page 3
 5/12/08
 VF

Content Uniformity

Chromatographic System

Resolution (R)
 (See page 2, Attachment A)

$$R = \frac{2(t_2 - t_1)}{w_1 + w_2} = \underline{21.7} \quad [\text{Limit: R is NLT 4.0}]$$

Theoretical Plates (N)
 (See page 3, Attachment A)

$$N = 16(t/w)^2 = \underline{6148} \quad [\text{Limit: N is NLT 1200}]$$

Tailing Factor (T)
 (See page 3, Attachment A)

$$T = [W_{0.05}/2f] = \underline{1.2} \quad [\text{Limit: T is NMT 2.0}]$$

Relative Std. Deviation (RSD)
 (See computer calculation, page 5)

$$RSD = \underline{0.33} \% \quad [\text{Limit: RSD is NMT 2.0\%}]$$

Standard 2 Calculation (ICV/Check Std.)
 (See pp. 3 - 8, Attachment A for chromatograms)

$$\% \text{ Digoxin} = \frac{\text{Area Std. 2}}{\text{Area Std. 1}} \times \frac{\text{Std 1 Wt.}}{\text{Std 1 Dilution}} \times \frac{\text{Std 2 Dilution}}{\text{Std 2 Wt.}} \times 100$$

Area Std. 1 = Avg. area of 5 std. injections. (See computer calculation, p. 5)

$$\text{Std. Wt. 1} = (2.522 \text{ mg})(0.961) = \underline{2.424 \text{ mg}}$$

$$\text{Std. Wt. 2} = (2.505 \text{ mg})(0.961) = \underline{2.407 \text{ mg}}$$

$$\% \text{ Digoxin} = \frac{1350936}{1358455} \times \frac{2.424 \text{ mg}}{100.0 \text{ ml}} \times \frac{100.0 \text{ ml}}{2.407 \text{ mg}} \times 100 = \underline{100.1 \%}$$

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.25 mg)	SAMPLE NO. 462753
ANALYST(S) <i>Valentino Trovelli</i>	ANALYST NO. 113	PAGE 4 OF 62 PAGES

SPL# 462753
 Back of Page 4
 5/14/08
 VF

Standard 1 Calculation (CCV)

(See pp. 3 - 7 and page 20, Attachment A for chromatograms)

$$\% \text{ Digoxin} = \frac{\text{Area Std.1}(\%) \times \text{Std 1 Wt.}}{\text{Area Std.1} \times \text{Std 1 Dilution}} \times \frac{\text{Std 1 Dilution}}{\text{Std 1 Wt.}} \times 100$$

Area Std.1 = Avg. area of 5 std. injections. (See computer calculation, p. 5)

Area Std.1(7) = Area of Std.1, Injection 7. (See page 20, Attachment A)

Std.Wt.1 = (2.522 mg)(0.961) = 2.424 mg

$$\% \text{ Digoxin} = \frac{1362718}{1358455} \times \frac{2.424 \text{ mg}}{100.0 \text{ ml}} \times \frac{100.0 \text{ ml}}{2.424 \text{ mg}} \times 100 = 100.3\%$$

Calculations

(See computer printout pages 6 - 7 for complete results and pages 9 - 13, Attachment A for chromatograms)
 + 15-19 Sample

Area Std.1 = Avg. area of 5 std. injections. (See computer calculation, p. 5)

Std.Wt.1 = (2.522 mg)(0.961) = 2.424 mg

If $98.5\% < X \leq 101.5\%$, then $M = X$

Range: 93.4% to 105.7%; Average(X): 98.7%; RSD: 3.5%; s: 3.47

Acceptance Value (AV) = $M - X + ks$

$$AV = (2.4) (3.47) = 8.33\%$$

(Limit: $AV \leq 15.0\%$ unless otherwise specified in the individual monograph)

General Continuation Sheet	Product: Digoxin Tablets (0.25 mg)	Sample No. 462753
Statistical Analysis of Data: Standard Solution 1 (CCV) 05/12/2008		
Relative STD Deviation	0.33 %	
Standard Deviation	4460.98825	
Average (mean)	1358454.8	
Number of entries	5	
Range	1351619 To	1361670
Data Entered:		
1351619 ✓		
1356187 ✓		
1361567 ✓		
1361231 ✓		
1361670 ✓		
Analyst(s) <i>Valentino Finelli</i>	Analyst No. 113	Page 5 of 12 Pages

General Continuation Sheet	Product: Digoxin Tablets (0.25 mg)	Sample No. 462753
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Content Uniformity

05/14/2008

No. of Units Examined	10
Standard Weight	2.424 mg.
Standard Dilution	100
Sample Dilution	10

Data Entered:

Unit #1	1375178	STD #1	1358455
Unit #2	1384606	Blank	0
Unit #3	1375132		
Unit #4	1444559		
Unit #5	1352004		
Unit #6	1382290		
Unit #7	1308413		
Unit #8	1351187		
Unit #9	1369343		
Unit #10	1481500		

CONTENT UNIFORMITY RESULTS:

	FOUND (mg/tablet)	DECLARED	% of DECLARED
UNIT #1	0.245	0.25	98.2
UNIT #2	0.247	mg/tablet	98.8
UNIT #3	0.245		98.2
UNIT #4	0.258		103.1
UNIT #5	0.241		96.5
UNIT #6	0.247		98.7
UNIT #7	0.233		93.4
UNIT #8	0.241		96.4
UNIT #9	0.244		97.7
UNIT #10	0.264		105.7
AVG.	0.247		98.7

OFFICIAL LIMITS:	90.0 %	TO	105.0 %
No. of Units Examined	10		
RANGE	93.4 %	TO	105.7 % of Declared
UNITS >=85 BUT <=115 % of Avg. Limit			10
UNITS >=75 BUT <85 OR >115 BUT <=125 % of Avg. Limit			0
UNITS <75 OR >125 % of Avg. Limit			0
REL. STD. DEV. :	3.5 LIMIT	<= 6.0%	

mg/unit = (R_spl * std_wt * spl_dil) / (R_std * std_dil * 1 unit)

Analyst(s) <i>Valentino Fariello</i>	Analyst No. 113	Page 6 of 12 Pages
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General Continuation Sheet	Product: Digoxin Tablets (0.25 mg)	Sample No. 462753
Statistical Analysis of Data:		
Content Uniformity Standard Deviation		05/14/2008
Relative STD Deviation	3.51 %	
Standard Deviation	3.47	
Average (mean)	98.67	
Number of entries	10	
Range	93.4 To 105.7	
Data Entered:		
98.2		
98.8		
98.2		
103.1		
96.5		
98.7		
93.4		
96.4		
97.7		
105.7		
Analyst(s) <i>Valentino Fucile</i>	Analyst No. 113	Page 7 of 12 Pages

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.25 mg)	SAMPLE NO. 462753
ANALYST(S) <i>Valentino Fiorelli</i>	ANALYST NO. 113	PAGE 8 OF 12 PAGES

FORM FDA 431a (5/84)

SPL# 462753
Back of Page 8
9/10/08
VF

Dissolution

Medium: 0.1N HCl, 500 ml (37.0°C ± 0.5°C)

Apparatus 1: 120 rpm

Time: 60 minutes

Instrument: Distek Dissolution Apparatus #1, FDA No. 1218
(QA by F.Maldonado on 7/7/08)

Instrument: Shimadzu Fluorescence Spectrophotometer, FDA# 5004459
(QA by V.Fiorella on 7/1/08)

Reagents: Sigma L-Ascorbic Acid, Lot 10X0256 (Rec'd before 4/10/06)
Sigma-Aldrich 30% H₂O₂, Batch# 04824AH (Rec'd 4/3/08)
Fisher Scientific Methanol, Lot 081717 (Rec'd 5/27/08)
Fisher Scientific HCl, Lot 068102 (Rec'd 5/4/07)

Filter: PALL Life Sciences Acrodisc Premium 25 mm Syringe Filter with
0.45 um GHP Membrane, Lot 21688684

Ascorbic acid-Methanol Solution

(Mettler Toledo AX205, FDA No. 5099471 - QA by D.Dai on 7/10/08)

202.2 mg Ascorbic acid ----> 100.0 ml MeOH

Hydrogen peroxide-Methanol Solution

Stock Solution: 2.0 ml 30% H₂O₂ ----> 100.0 ml MeOH (Refrigerate)

Working Solution: 2.0 ml Stock ----> 100.0 ml MeOH

Standard Solutions

(Mettler Toledo AX205, FDA No. 5099471 - QA by D.Dai on 7/10/08)

Stock Solution

25.09 mg USP Digoxin RS ----> 500.0 ml Dilute Alcohol (4 in 5)

10.0 ml
-----> 100.0 ml Dilute Alcohol (4 in 5) [0.005 mg/ml]

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.25 mg)	SAMPLE NO 462753
ANALYST(S) <i>Valentino Fioell</i>	ANALYST NO. 113	PAGE 9 OF 12 PAGES

SPL# 462753
 Back of Page 9
 9/11/08
 VF

Working Standard Solutions

Standard Solution	ml Stock Solution	ml Dissolution Medium	Final Concentration (mg/ml)
20%	1.0	50.0	0.00010
40%	2.0	50.0	0.00020
60%	3.0	50.0	0.00030
80%	4.0	50.0	0.00040
100%	5.0	50.0	0.00050

Test Solution (6 tablets tested; 0.25 mg/tablet)

1 tablet ---> 0.1N HCl, 500 ml ---> Filter [0.0005 mg/ml]

Procedure

Test Prep.: 1.0 ml Test Solution (Prepared in duplicate)
 + 1.0 ml Ascorbic acid-Methanol Solution
 + 5.0 ml HCl
 + 1.0 ml Hydrogen peroxide-Methanol Solution
 ----> Glass-stoppered flask

Std. Preps.: 1.0 ml of each Working Std. Solution
 + 1.0 ml Ascorbic acid-Methanol Solution
 + 5.0 ml HCl
 + 1.0 ml Hydrogen peroxide-Methanol Solution
 ----> Glass-stoppered flask

Blank Prep.: 1.0 ml Dissolution Medium
 + 1.0 ml Ascorbic acid-Methanol Solution
 + 5.0 ml HCl
 + 1.0 ml Hydrogen peroxide-Methanol Solution
 ----> Glass-stoppered flask

Procedure

After 2 hours (FDA Timer# 1678 - QA by A.Vargas on 1/18/08), measure the fluorescence of each preparation at an emission wavelength of about 485 nm and an excitation wavelength of about 372 nm correcting each reading for the blank.

Plot a standard curve of Fluorescence vs. % Dissolution.

Determine the % dissolution of digoxin for each Test Solution from the graph.

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.25 mg)	SAMPLE NO. 462753
ANALYST(S) <i>Valentino Fiacco</i>	ANALYST NO. 113	PAGE 10 OF 12 PAGES

SPL# 462753
 Back of Page 10
 9/12/08
 VF

Results

See least squares line fitting calculation, pages 11-12, and Attachment B for spectra.

<u>Name</u>	<u>EM @ 485 nm</u>	<u>Corrected EM @ 485 nm</u>
Blank	-0.046	0
20% Std. Solution	0.885	0.931
40% Std. Solution	1.768	1.814
60% Std. Solution	2.678	2.724
80% Std. Solution	3.699	3.745
100% Std. Solution	4.724	4.77
Tablet 1-Test 1	4.911	4.957
Tablet 1-Test 2	4.932	4.978
Tablet 2-Test 1	4.962	5.008
Tablet 2-Test 2	4.689	4.735
Tablet 3-Test 1	4.404	4.45
Tablet 3-Test 2	4.481	4.527
Tablet 4-Test 1	4.159	4.205
Tablet 4-Test 2	4.158	4.204
Tablet 5-Test 1	4.17	4.216
Tablet 5-Test 2	4.268	4.314
Tablet 6-Test 1	5.077	5.123
Tablet 6-Test 2	4.816	4.862
100% Std. Solution	4.886	4.932

<u>Tablet</u>	<u>% Dissolution 1</u>	<u>% Dissolution 2</u>	<u>Avg. % Dissolution</u>
1	104.96	105.4	105.18
2	106.02	100.34	103.18
3	94.41	96.01	95.21
4	89.31	89.29	89.30
5	89.54	91.58	90.56
6	108.42	102.98	105.70
AVG			98.19

[Limit: Each unit is NLT Q + 5% (Q=80%) for 6 units tested (Stage 1)]

General Continuation
Sheet

Product: Digoxin Tablets (0.25 mg)

Sample No.

462753

Least Squares Line Fitting

09/12/2008

The Line Fitting used is $Y = mX + b$ with $m = 0.048045$ and $b = -0.0859$

Correlation Coefficient = 0.999366014

Data Entered:

	x	y	LSLF y	% Deviation
20% Std.	20	0.931	0.875	6.400
40% Std.	40	1.814	1.8359	1.193
60% Std.	60	2.724	2.7968	2.603
80% Std.	80	3.745	3.7577	0.338
100% Std.	100	4.77	4.7186	1.089

Extrapolated Data:

	X	Y
Tablet 1-Test 1	104.96	4.9570
Tablet 1-Test 2	105.40	4.9780
Tablet 2-Test 1	106.02	5.0080
Tablet 2-Test 2	100.34	4.735
Tablet 3-Test 1	94.41	4.45
Tablet 3-Test 2	96.01	4.527

Analyst(s)

Valentino Ferrell

Analyst No.

113

Page 11 of 12 Pages

General Continuation
Sheet

Product: Digoxin Tablets (0.25 mg)

Sample No.

462753

Least Squares Line Fitting

09/12/2008

The Line Fitting used is $Y = mX + b$ with $m =$ 0.048045and $b =$ -0.0859

Correlation Coefficient = 0.999366014

Data Entered:

	X	Y	LSLF y	% Deviation
20% Std.	20	0.931	0.875	6.400
40% Std.	40	1.814	1.8359	1.193
60% Std.	60	2.724	2.7968	2.603
80% Std.	80	3.745	3.7577	0.338
100% Std.	100	4.77	4.7186	1.089

Extrapolated Data:

	X	Y
Tablet 4-Test 1	89.31	4.2050
Tablet 4-Test 2	89.29	4.2040
Tablet 5-Test 1	89.54	4.2160
Tablet 5-Test 2	91.58	4.314
Tablet 6-Test 1	108.42	5.123
Tablet 6-Test 2	102.98	4.862

Analyst(s)

*Valentino Finelli*Analyst No.
113

Page 12 of 12 Pages

ATTACHMENT A - Page / of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 462753

Name: Blank

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\462753\Blank-Rep2

Date: 05/12/2008 10:44:34 AM

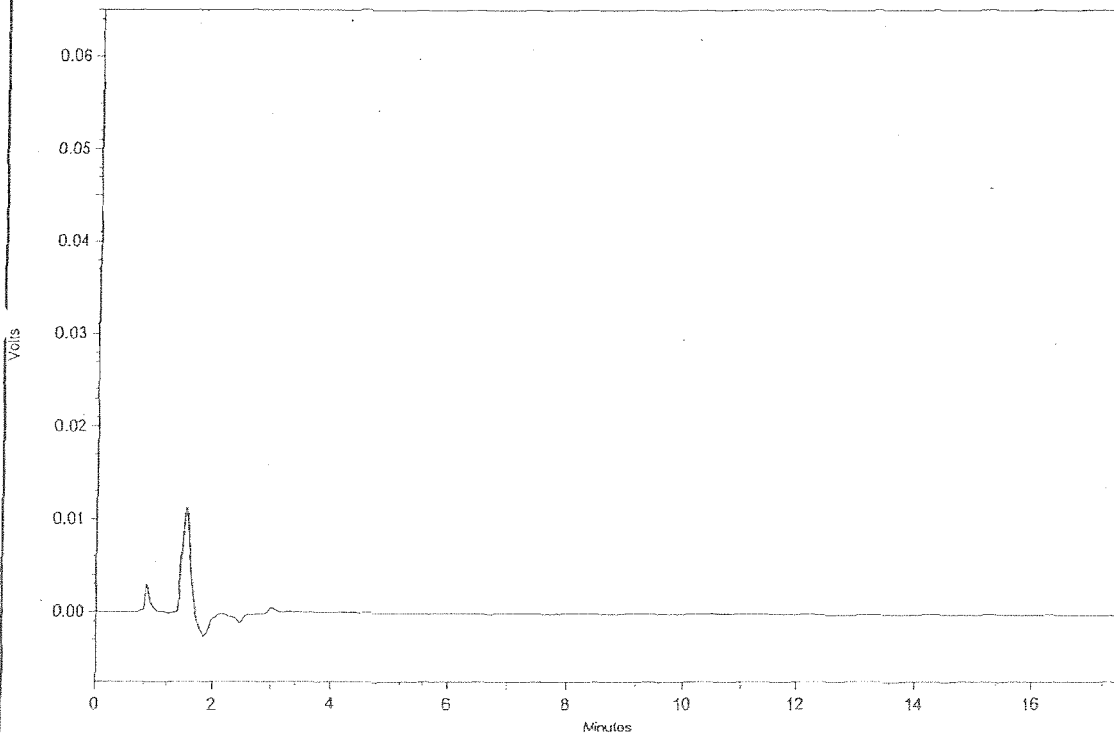
Vial: 0

Injection Volume: 50 ul

Detector A

(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
------	------	----------------	------	--------	-----------	------------	--------------------



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 4/7/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 2 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 462753

Name: System Suitability Solution

Method: C:\CLASS-VP\METHODS\DigoxinTabs.mel

File: C:\CLASS-VP\DATA\DigoxinTabs\462753\SysSuitSoln

Date: 05/12/2008 11:03:33 AM

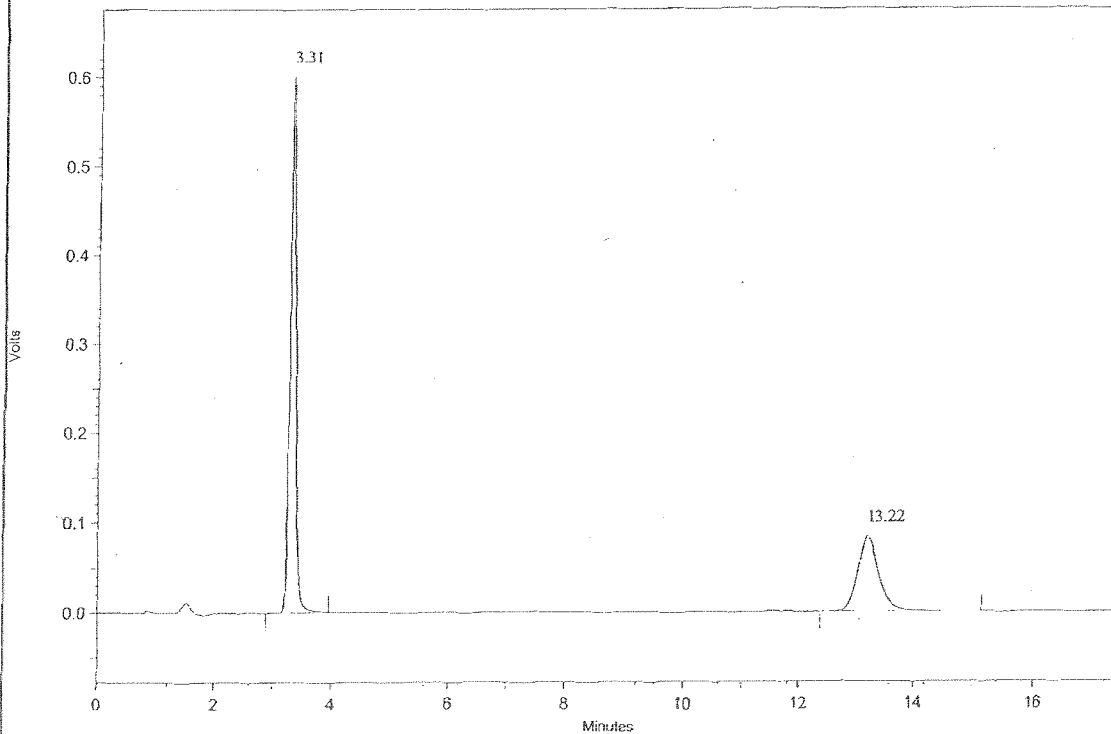
Vial: 1

Injection Volume: 50 ul

Detector A
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxigenin	3.31	4333429	600365	1.2	0.0	3053
2	Digoxin	13.22	2167452	83434	1.2	21.7	6177

Totals			6500881	683799			
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Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 4/7/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 3 of 20 pages

Product: Digoxin Tablets (0.25 mg)

SpLNo. 462753

Name: Standard Solution 1 (CCV)

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\462753\Std.Soln-Rep1.

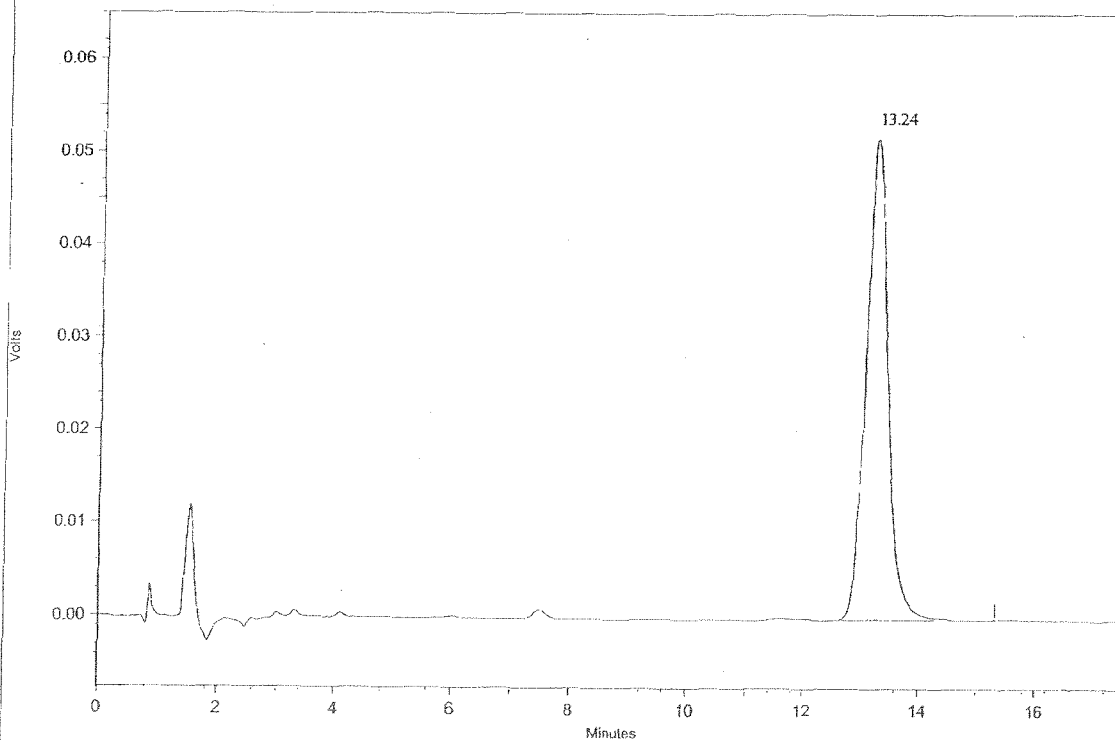
Date: 05/12/2008 11:22:33 AM

Vial: 2

Injection Volume: 50 ul

Detector A
(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.24	1351619	51848	1.2	0.0	6148
Totals			1351619	51848			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 4/7/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 4 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 462753

Name: Standard Solution 1 (CCV)

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\462753\Std.Soln-Rep2

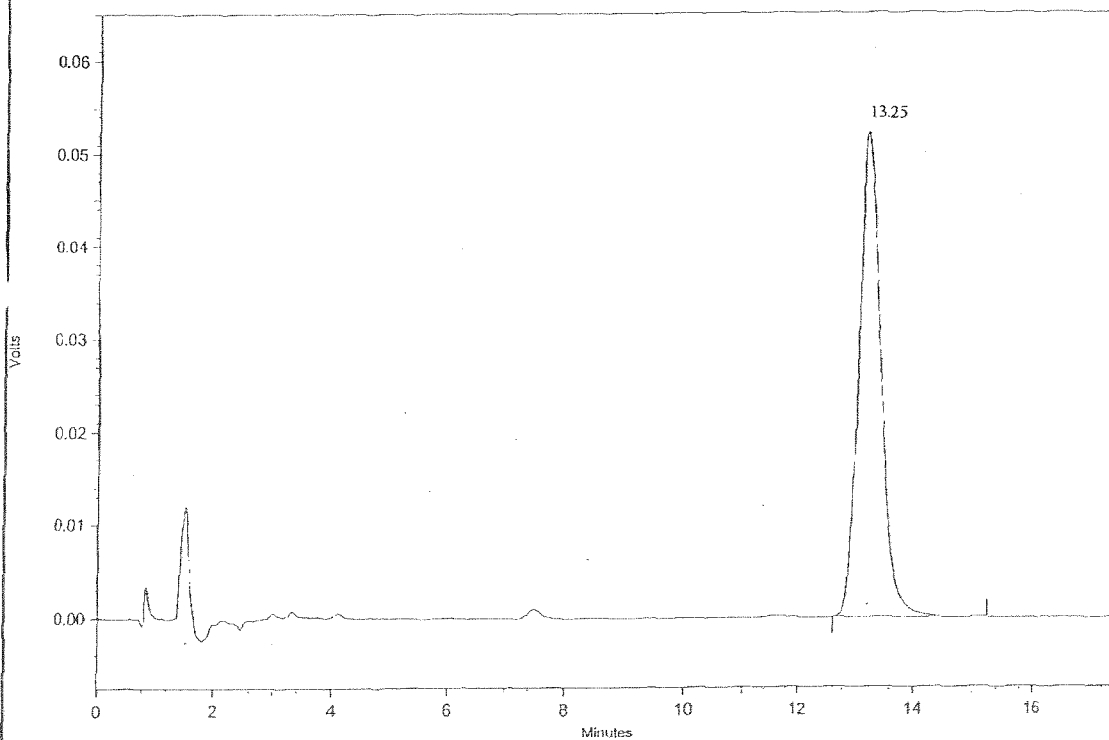
Date: 05/12/2008 11:41:28 AM

Vial: 2

Injection Volume: 50 ul

Detector A
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.25	1356187	52219	1.2	0.0	6197
Totals			1356187	52219			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 4/7/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 5 of 20 pages

Product: Digoxin Tablets (0.25 mg)

SpLNo. 462753

Name: Standard Solution 1 (CCV)

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\462753\Std.Soln-Rep3.

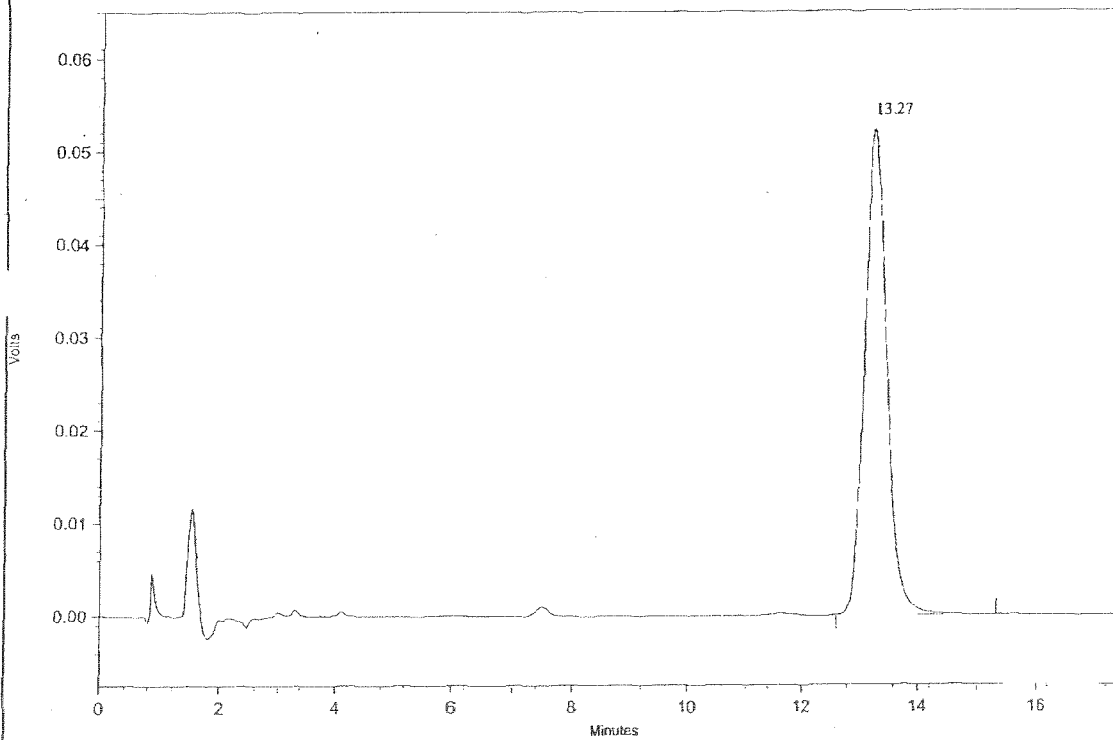
Date: 05/12/2008 12:00:29 PM

Vial: 2

Injection Volume: 50 ul

Detector A
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.27	1361567	52314	1.2	0.0	6170
Totals			1361567	52314			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 4/7/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 6 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 462753

Name: Standard Solution 1 (CCV)

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\462753\Std.Soln-Rep4.

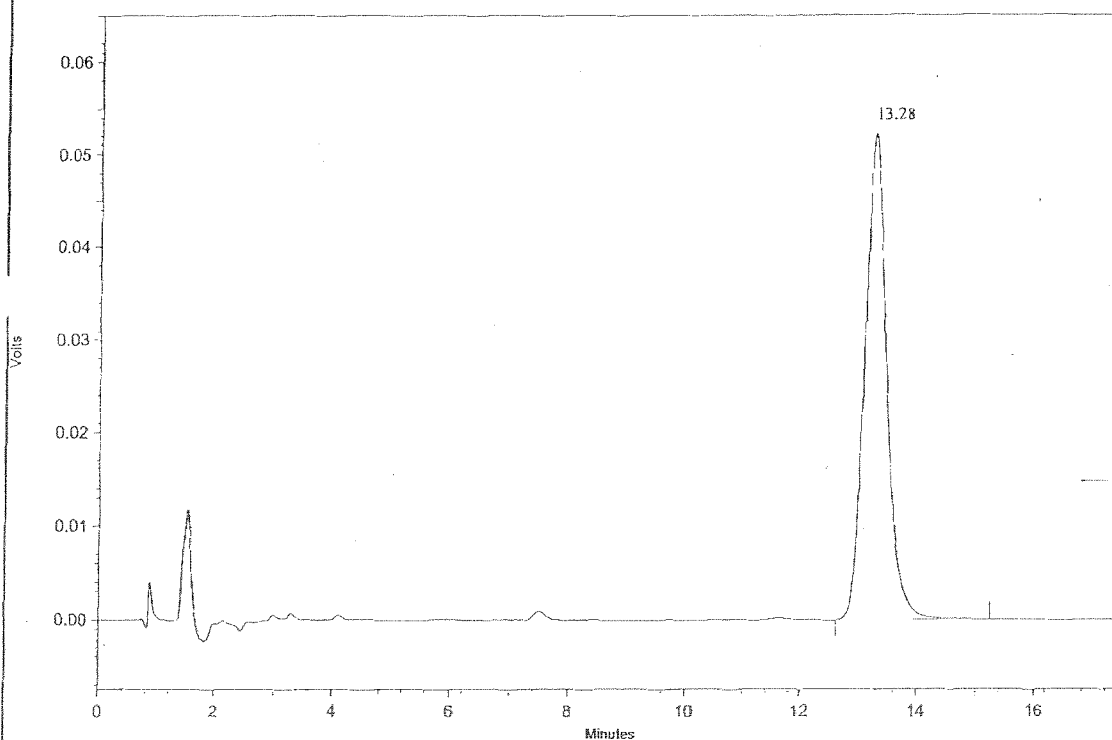
Date: 05/12/2008 12:19:28 PM

Vial: 2

Injection Volume: 50 ul

Detector A
(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.28	1361231	52233	1.2	0.0	6191
Totals			1361231	52233			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 4/7/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 7 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 462753

Name: Standard Solution 1 (CCV)

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\462753\Std.Soln-Rep5.

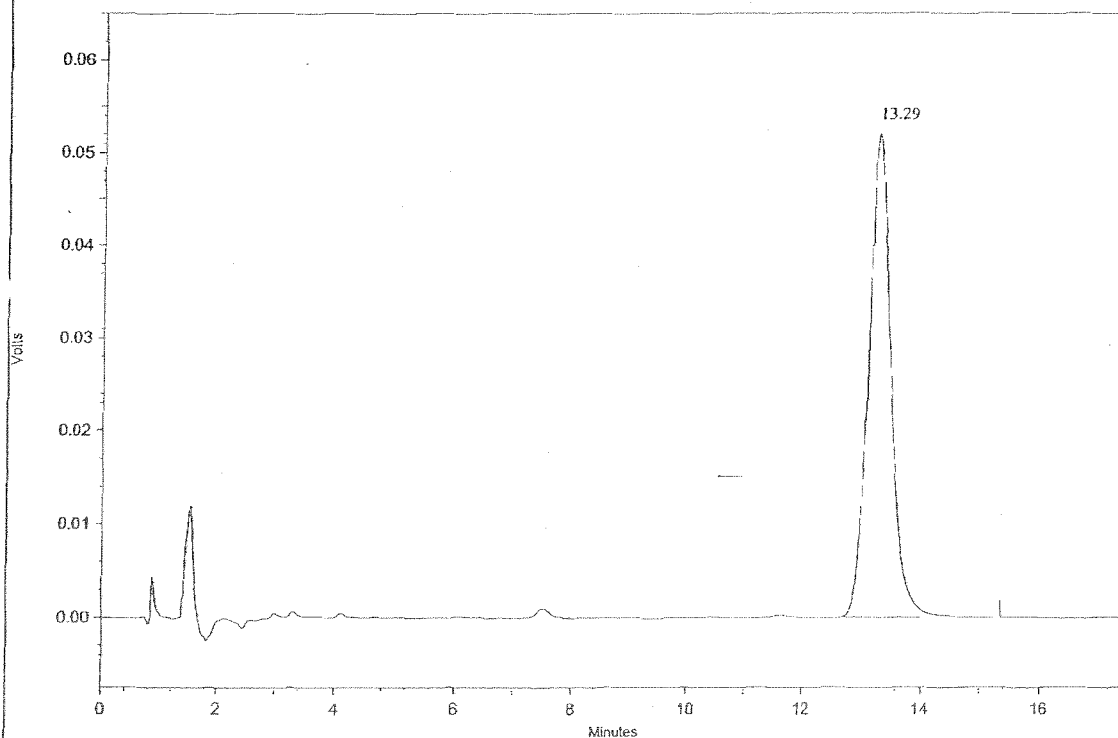
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Vial: 2

Injection Volume: 50 ul

Detector A
(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.29	1361670	52059	1.2	0.0	6098
Totals			1361670	52059			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 4/7/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 8 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 462753

Name: Standard Solution 2 (ICV)

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\462753\CheckStd.

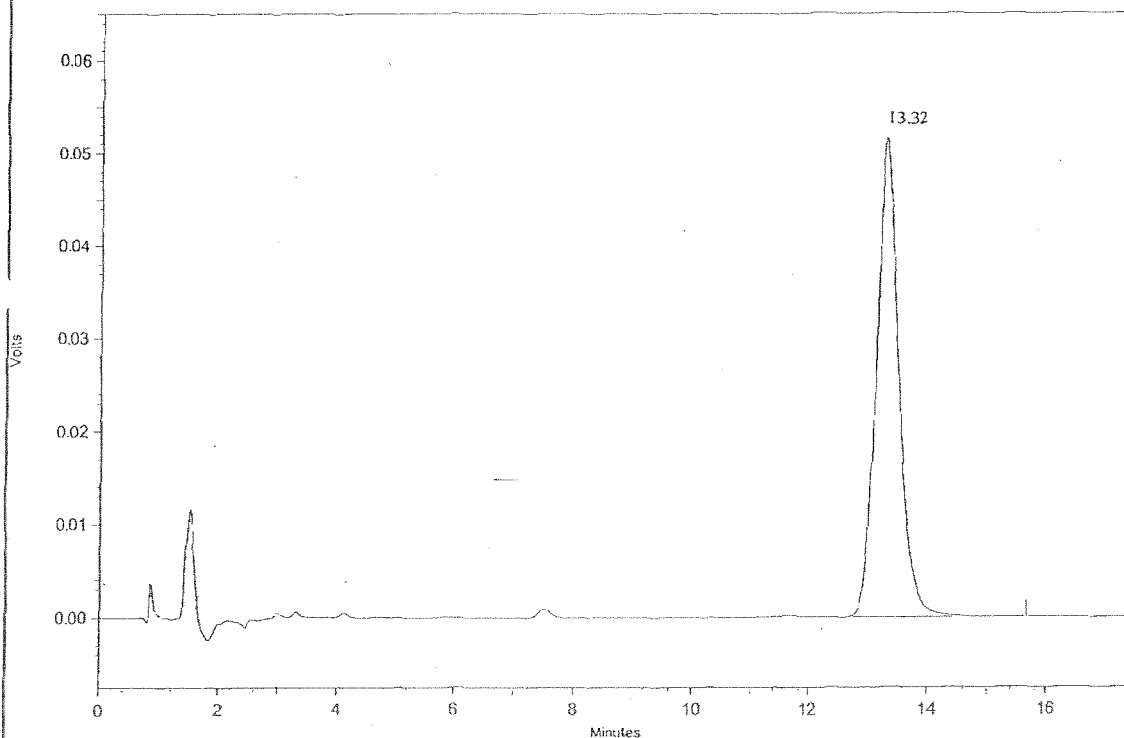
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Vial: 3

Injection Volume: 50 ul

Detector A
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.32	1350936	51585	1.2	0.0	6179
Totals			1350936	51585			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 4/7/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 9 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 462753

Name: Tablet 1

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\462753\Tab1

Date: 05/12/2008 2:47:06 PM

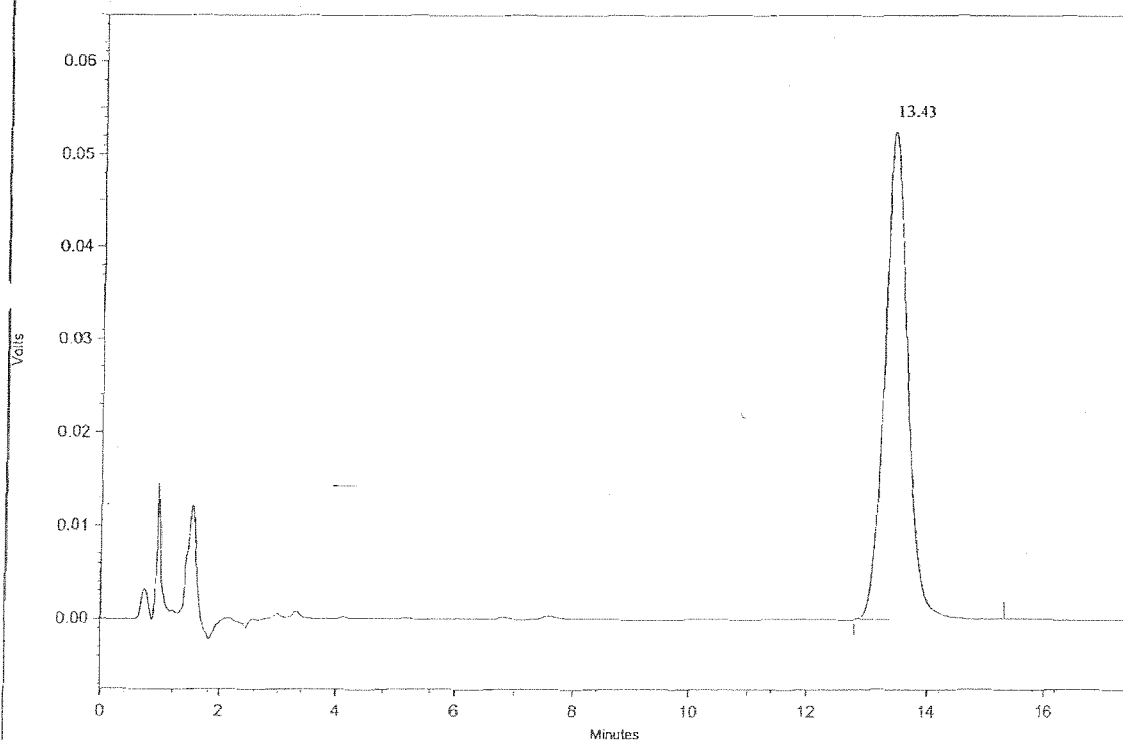
Vial: 4

Injection Volume: 50 ul

Detector A

(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.43	1375178	52490	1.2	0.0	6259
Totals			1375178	52490			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 4/7/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 10 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 462753

Name: Tablet 2

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\462753\Tab2

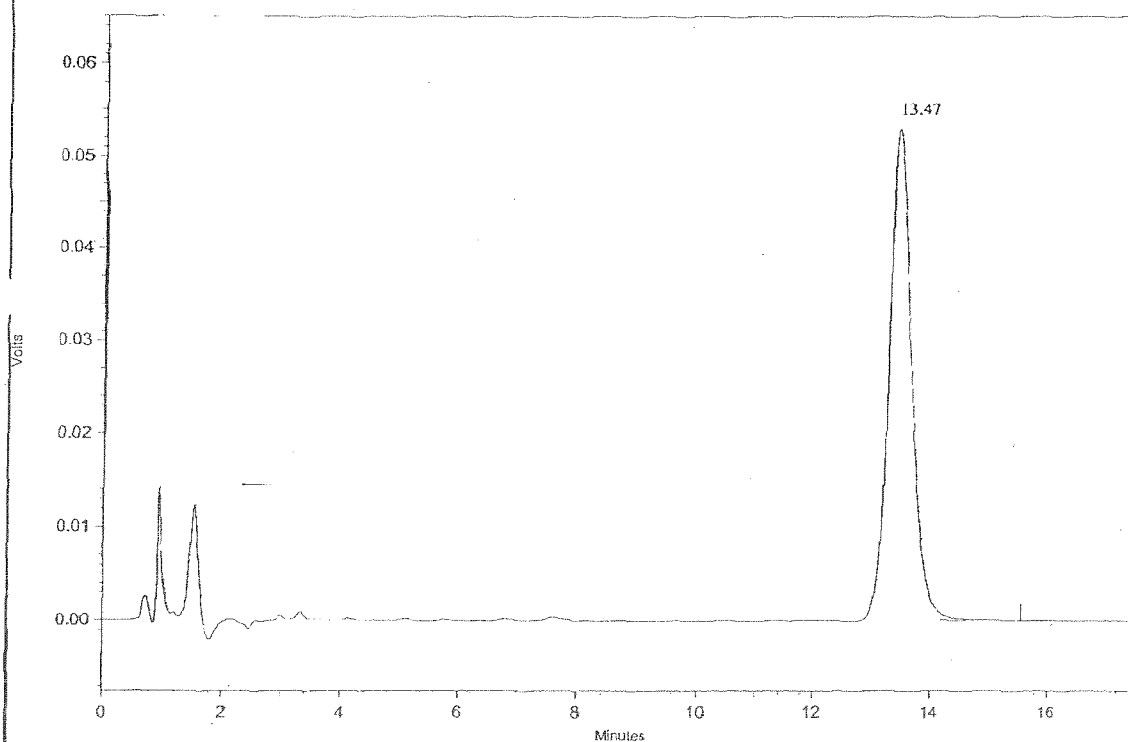
Date: 05/12/2008 3:06:02 PM

Vial: 5

Injection Volume: 50 ul

Detector A
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.47	1384606	52825	1.2	0.0	6295
Totals			1384606	52825			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 4/7/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page // of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 462753

Name: Tablet 3

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\462753\Tab3

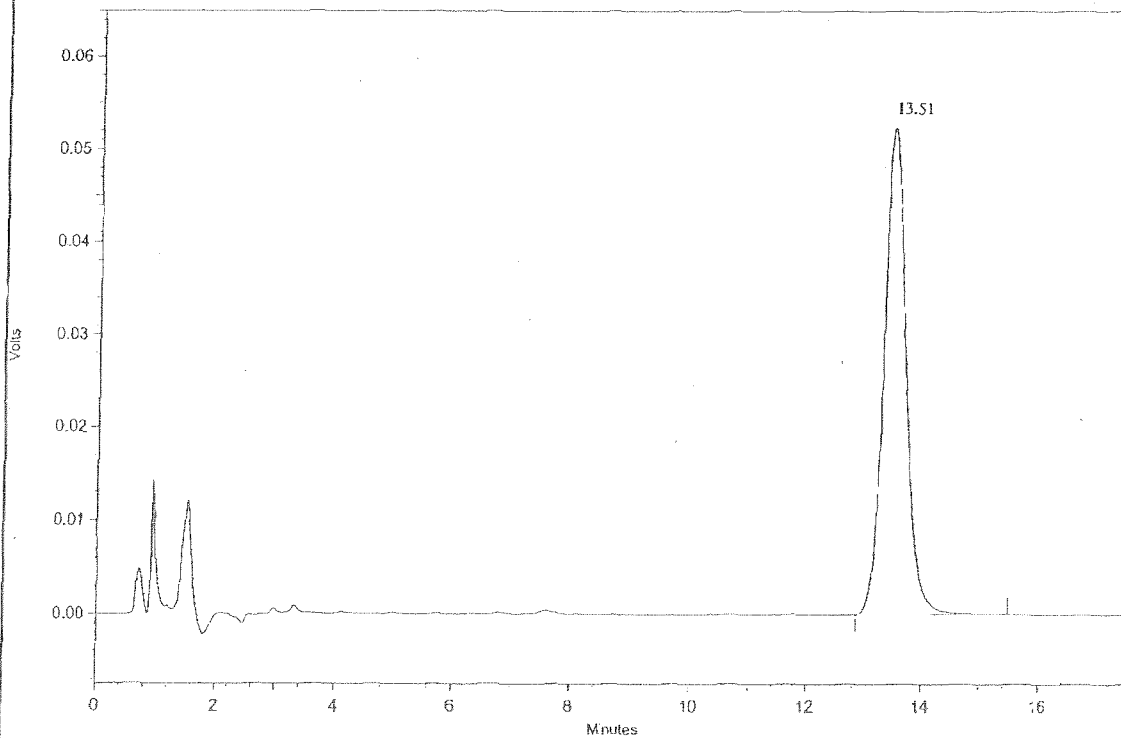
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Vial: 6

Injection Volume: 50 ul

Detector A
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.51	1375132	52357	1.1	0.0	6279
Totals			1375132	52357			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 4/7/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 62 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 462753

Name: Tablet 4

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\462753\Tab4

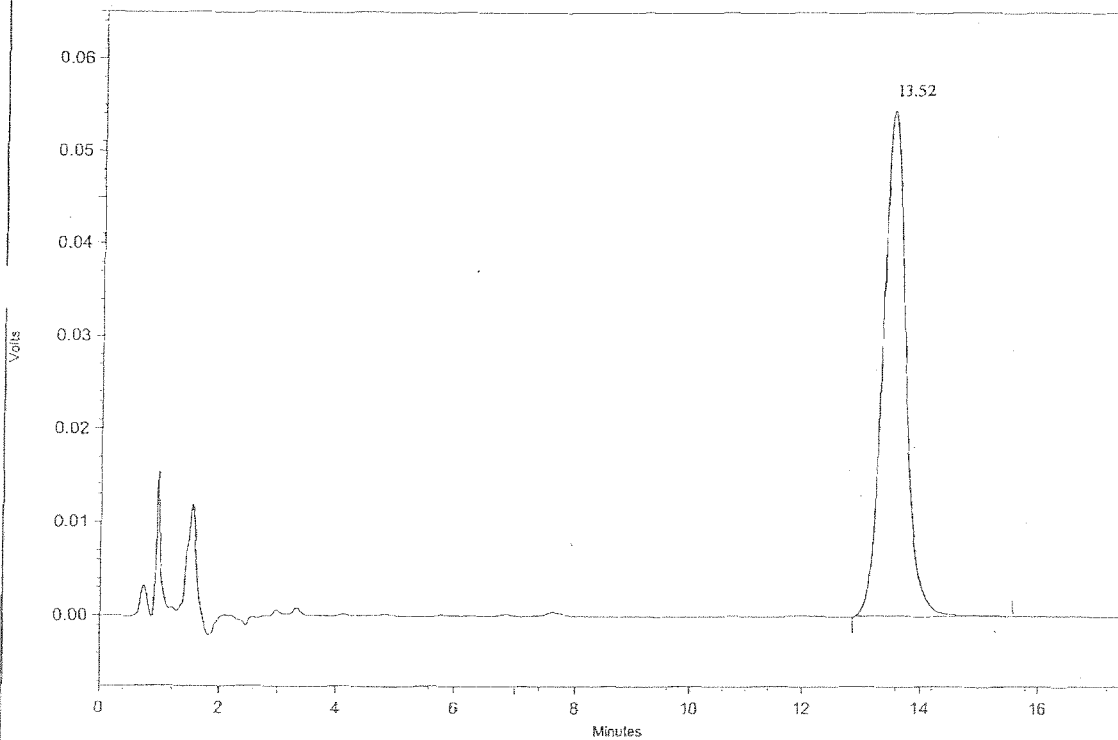
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Vial: 7

Injection Volume: 50 ul

Detector A
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.52	1444559	54489	1.1	0.0	6019
Totals			1444559	54489			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 4/7/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 13 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 462753

Name: Tablet 5

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\462753\Tab5

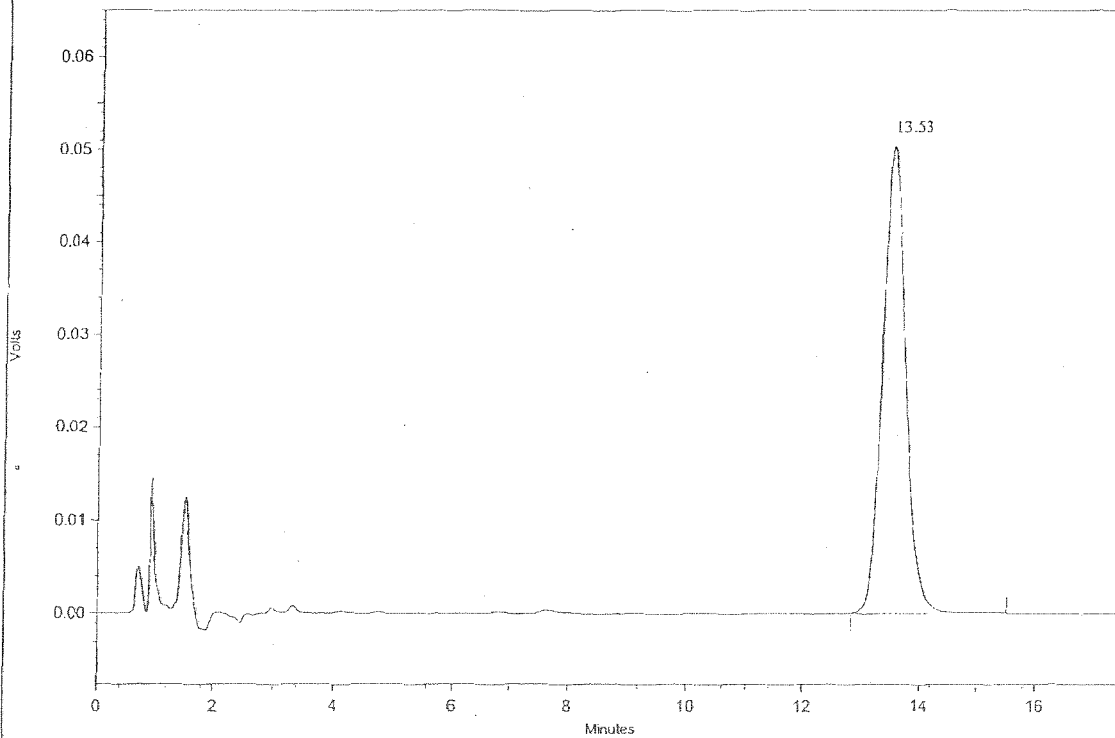
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Vial: 8

Injection Volume: 50 μ lDetector A
(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.53	1352004	50382	1.1	0.0	6002

Totals			1352004	50382			
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Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 4/7/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 μ m), Serial No. 88682C

ATTACHMENT A - Page 14 of 20 pages

Product: Digoxin Tablets (0.25 mg)

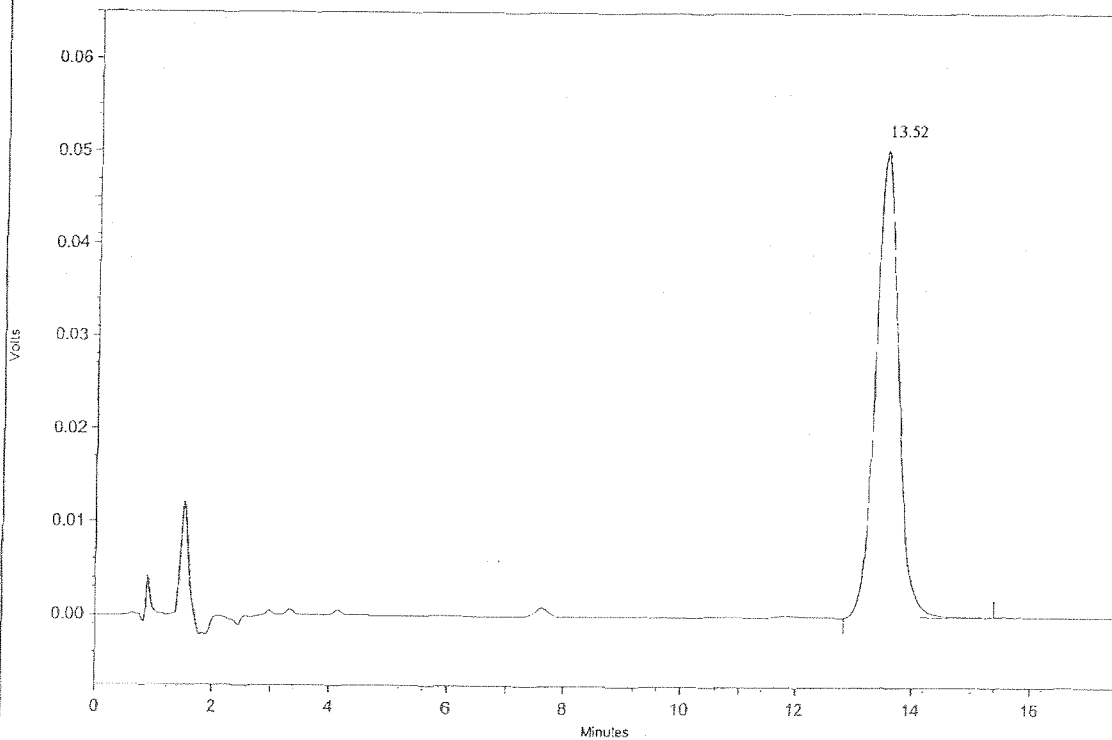
Spl.No. 462753

Name: Standard Solution 1 (CCV)
Method: C:\CLASS-VP\METHODS\DigoxinTabs.met
File: C:\CLASS-VP\DATA\DigoxinTabs\462753\Std.Soln.6
Date: 05/12/2008 4:21:55 PM
Vial: 2
Injection Volume: 50 ul

Detector A
(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.52	1359785	50307	1.1	0.0	5809

Totals			1359785	50307			
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Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 4/7/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 15 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 462753

Name: Tablet 6

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\462753\Tab6

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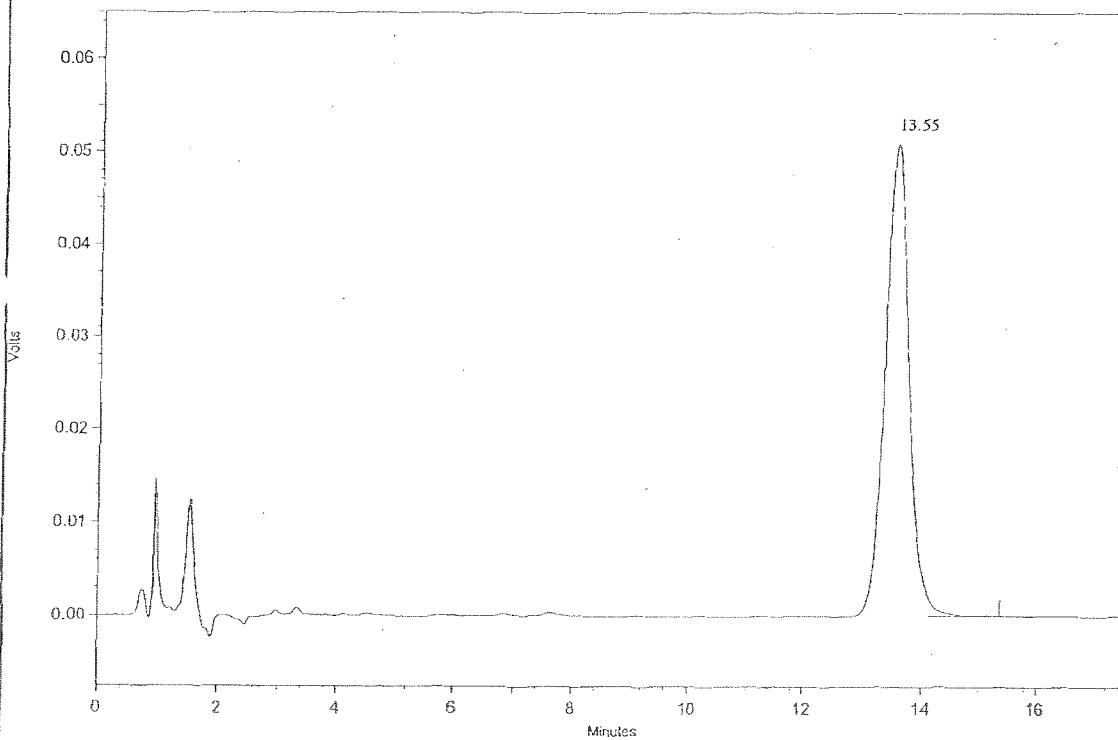
Vial: 9

Injection Volume: 50 ul

Detector A
(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.55	1382290	50811	1.1	0.0	5739

Totals			1382290	50811			
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Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 4/7/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 16 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 462753

Name: Tablet 7

Method: C:\CLASS-VP\METHODS\Digoxin\Tabs.met

File: C:\CLASS-VP\DATA\Digoxin\Tabs\462753\Tab7

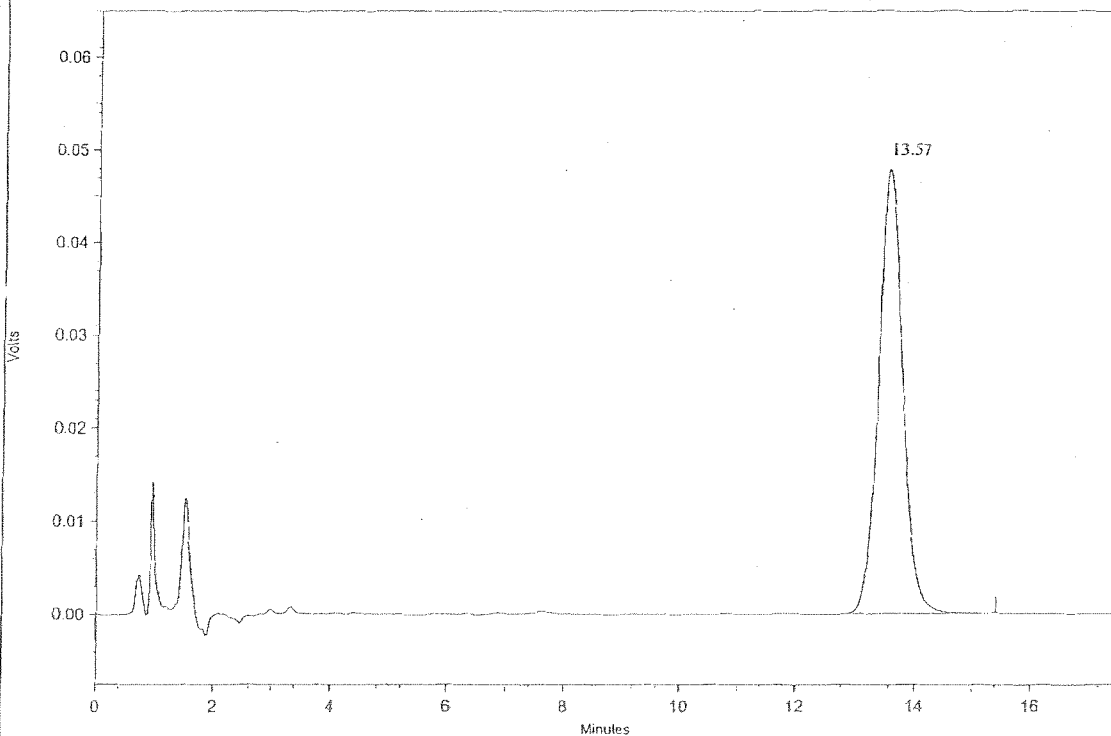
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Vial: 10

Injection Volume: 50 ul

Detector A
(218nm)

PK #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.57	1308413	47846	1.1	0.0	5798
Totals			1308413	47846			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 4/7/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 17 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 462753

Name: Tablet 8

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\462753\Tab8

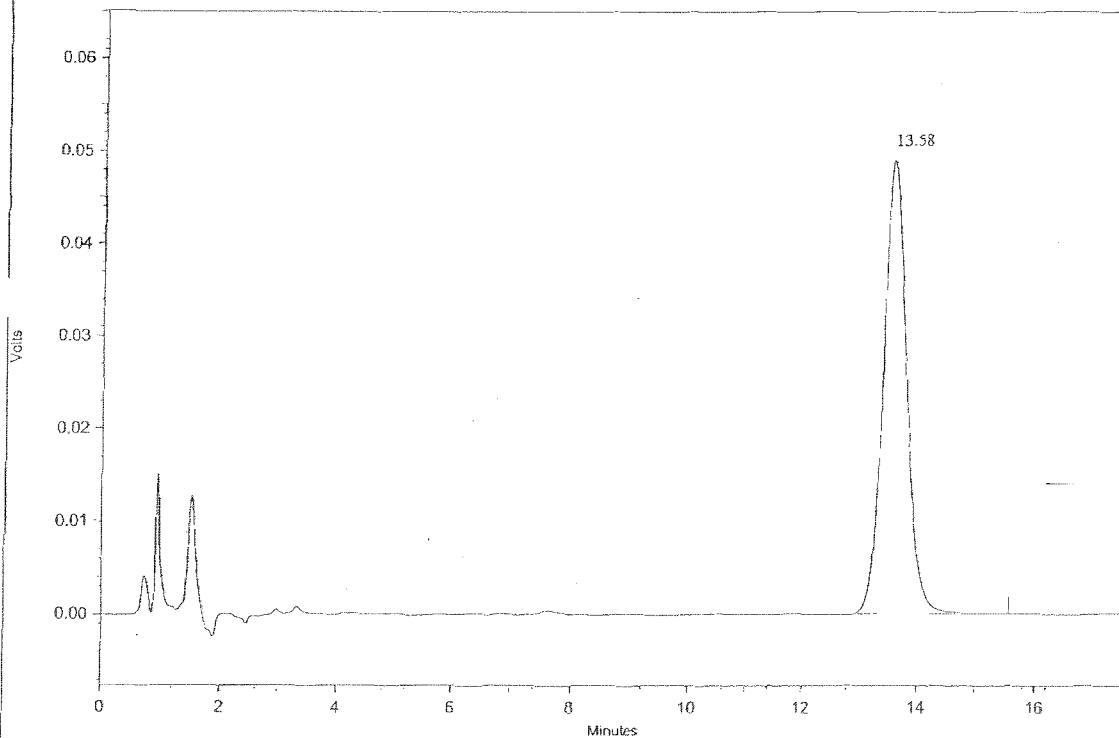
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Vial: 11

Injection Volume: 50 ul

Detector A
(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.58	1351187	48953	1.1	0.0	5606
Totals			1351187	48953			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 4/7/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 18 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 462753

Name: Tablet 9

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\462753\Tab9

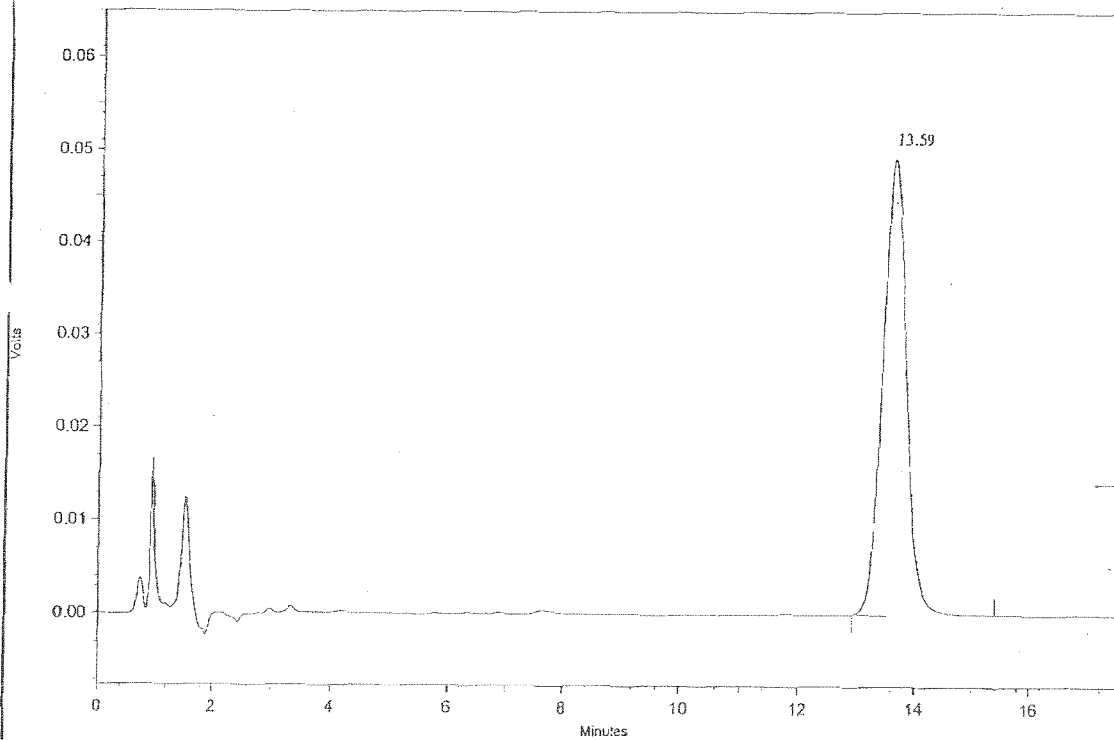
Date: 05/12/2008 5:37:49 PM

Vial: 12

Injection Volume: 50 ul

Detector A
(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.59	1369343	49220	1.1	0.0	5560
Totals			1369343	49220			



Instrument: Shinadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V. Fiorella on 4/7/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 19 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 462753

Name: Tablet 10

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\462753\Tab10

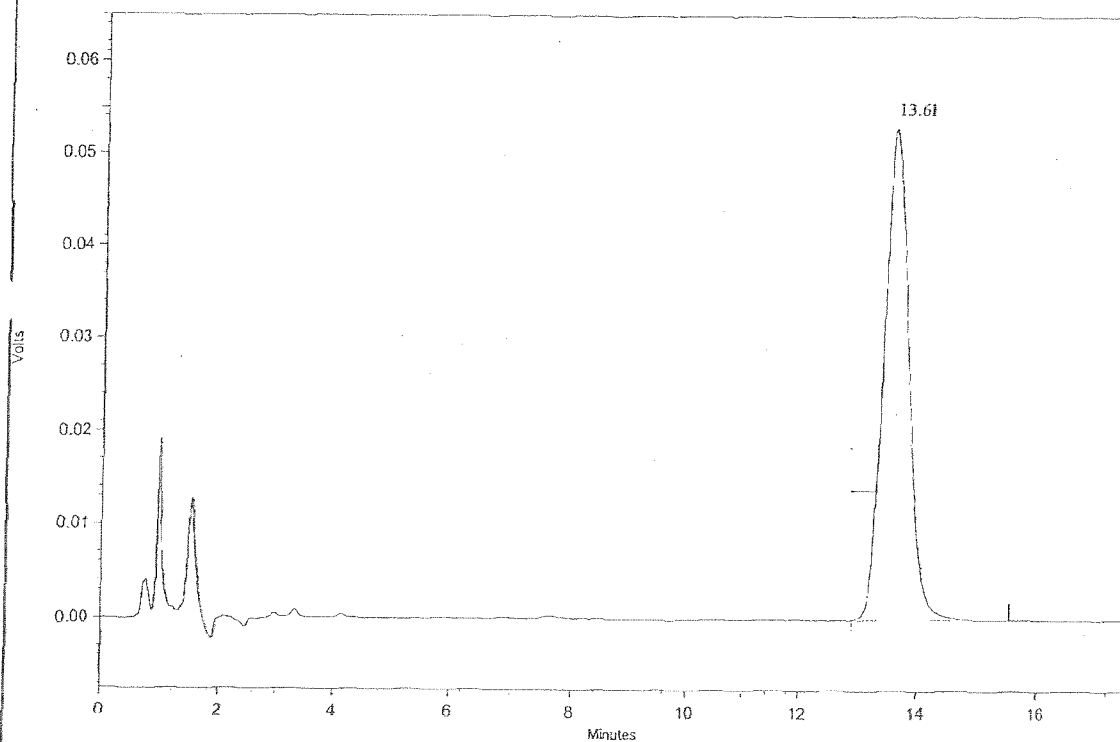
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Vial: 13

Injection Volume: 50 ul

Detector A
(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.61	1481500	52900	1.1	0.0	5438
Totals			1481500	52900			



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V. Fiorella on 4/7/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

ATTACHMENT A - Page 20 of 20 pages

Product: Digoxin Tablets (0.25 mg)

Spl.No. 462753

Name: Standard Solution I (CCV)

Method: C:\CLASS-VP\METHODS\DigoxinTabs.met

File: C:\CLASS-VP\DATA\DigoxinTabs\462753\Std.Soln.7

Date: 05/12/2008 6:15:46 PM

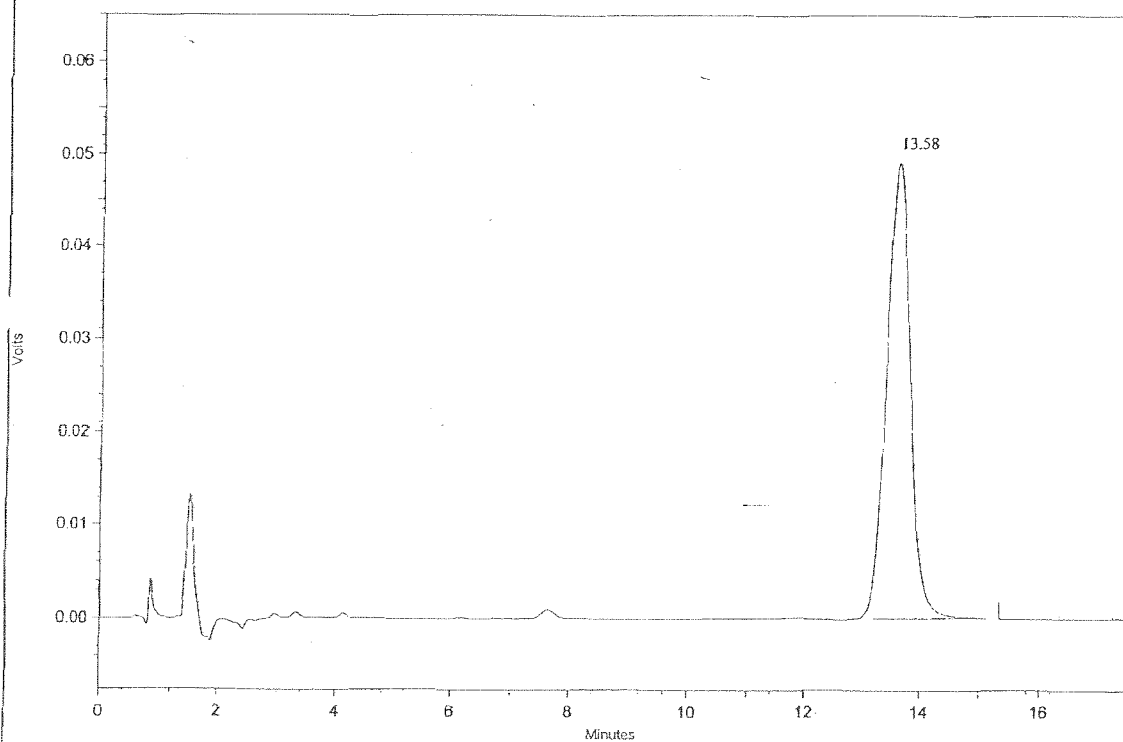
Vial: 2

Injection Volume: 50 ul

Detector A
(218nm)

Pk #	Name	Retention Time	Area	Height	Asymmetry	Resolution	Theoretical plates
1	Digoxin	13.58	1362718	49101	1.1	0.0	5547

Totals			1362718	49101			
--------	--	--	---------	-------	--	--	--



Instrument: Shimadzu HPLC LC-10AT VP, FDA# 5083845 (QA by V.Fiorella on 4/7/08)

Analyst: Valentino Fiorella

Mobile Phase: Acetonitrile/Water (26/74)

Flow: 2.0 ml/min.

Column: Supelcosil LC-18-DB (250 mm x 4.6 mm; 5 um), Serial No. 88682C

Food and Drug Administration Office of Regulatory Affairs Collection Report

For Sample Number: 462746

This is an accurate reproduction of the original electronic record as of 04/02/2008

Dr-174

Flag	Flag Remarks				
Survey Sample	CDER Survey 2008-800				
Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic	Surveillance	Official	0886991	Completed
FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
3006697890	03/21/2008	63FCC06	Manufacturer	56008A	3
Compliance Num	Country of Origin				
	United States				
Related Smpl Num	Position Class	Sampling District	NDC Number	Permit Number	Storage Rqrmnt.
462744	DAP	SAN-DO	51079-945-66		Ambient
Dealer is Consumer	Crx/DEA Schedule	Recall Num	Consumer Compl. Num	Brand Name	
No				Digitex	

Product Description

Digoxin Tablets, 125 mcg, RX, single ingredient

Product Label

See continuation.

Reason for Collection

FY 2008 Low Cost Generic Drug Sample Survey 2008-800 (CP 7356.008). Analyze for Uniformity of Dosage Units; Dissolution; Identification

MFG Codes

Printed in ink on side of bottle: "Lot No.: 7P964"

Expiration Date

"Exp. Date: 4/09"

Firm Legal Name	Address	Type of Firm	Firm FEI	FCE
Walmart Stores Inc	13232 11th Avenue Hanford, CA 93230-9591 US	Dealer	3005072736	
AMIDE PHARMACEUTICALS INC.	101 E Main St Little Falls, NJ 07424-5608 US	Manufacturer	3006697890	

Size of Lot	Est. Value	Rcpt Type	Carrier Name	Date Shipped
(b) (4) tablet bottles		FDA484		

RECEIVED

Description of Sample

Sample consists of two boxes of Digoxin Tablets, USP, 125 mcg

Method of Collection

Collected at random from lot on shelves at dealer.

How Prepared

Sample id'd as below and placed into brown paper bag. Brown paper bag id'd as below and sealed as below. Packed to ship.

Collector's Identification on Package and/or Label

"462746 03/21/08 LCL"

Collector's Identification on Seal

"462746 03/25/08 Lillian C. Lopez"

Sample Delivered To

Fed-Ex

Date Delivered

03/25/2008

Orig C/R & Records To

SAN-DO

Lab w/Split Sample

0

Lab

NRL

Document Number	Document Date	Document Type	Document Remarks
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Remarks

Sample collected on 3-21-08, held under lock and key, and sealed and shipped on 3-25-08.

Date: 04/02/2008

Page: 1 of 3